UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	Subcategory No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., Civil Action No. 06-11337-PBS;	Hon. Patti B. Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS; and	
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Boehringer Ingelheim Corp., et al., Civil Action No. 07-10248-PBS	

SURREPLY TO REPLY BRIEFS OF ABBOTT, DEY, AND ROXANE IN SUPPORT OF MOTIONS TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

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INTRODUCTION

This brief responds to the Reply Briefs of Dey, Roxane and Abbott in the three federal cases (Master Dkt. Nos. 6681, 6678 and 6677). The majority of the arguments, cases and documents cited by the defendants in their reply briefs are mere repeats of what was presented in their opening briefs. Relator, Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care" or "VAC") attempts to limit this combined surreply to new arguments or different iterations of the arguments to avoid repetition.

ARGUMENT

I. DEFENDANTS' ATTEMPT TO USE THE PUBLIC DISCLOSURE BAR TO DISMISS RELATOR FROM THESE CASES MISCONSTRUES THE LANGUAGE AND INTENT OF THE FALSE CLAIMS ACT

The False Claims Act has been aptly described by the GAO as "one of the government's primary weapons to fight fraud against the government." GAO-06-320R, January 31, 2006 (letter transmitting report to Congress); *see also Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 792 (2000) (Stevens, J., dissenting) ("The False Claims Act is used as… the primary vehicle by the Government for recouping losses suffered through fraud," citing Congressional report). As this Court has noted, "the terms of the FCA must be read liberally in accordance with their remedial purpose." *United States ex rel. Franklin v. Parke-Davis,* 147 F. Supp. 2d. 39, 53 (D. Mass. 2001) (citing *United States v. Neifert-White Co.*, 390 U.S. 228, 232-233 (1968)). The public disclosure bar in the current statute is a favorite defense against *qui tam* actions, and as a result is one of the statute's most frequently litigated provisions. Applying this conditional, jurisdiction-stripping feature in a manner consistent with Congressional intent requires, first of all, viewing it thorough the prism of the historical development of the False Claims Act.

Congress has amended the statute from time to time since 1863 in an effort to encourage

whistle-blowing while simultaneously discouraging merely opportunistic behavior. After adopting the restrictive "government knowledge" bar in 1943, Congress learned in the mid-1980s that it had largely stifled *qui tam* actions for four decades, to the detriment of the federal treasury. Congress's overarching purpose in amending the False Claims Act again in 1986 was to remedy that unintended consequence by encouraging relators to file *qui tam* cases.

One of the most important changes Congress made to accomplish that purpose was to repeal the "government knowledge" bar and replace it with the current "public disclosure" provisions and the "original source" exception. *United States ex rel. Dunleavy v. County of Delaware*, 123 F.3d 734, 745-746 (3d Cir.1997) ("Congress undertook the amending of the FCA to eliminate the draconian 'government knowledge' standard applied since 1943"). Despite a clear liberalizing intent, the public disclosure bar adopted in 1986 to replace the discarded government knowledge bar has been misinterpreted by some courts to create obstacles to *qui tam* actions that were never contemplated by Congress and that directly contravene what Congress intended its amendments to accomplish. *See United States ex rel. Minn. Ass'n of Nurse Anesthetists v. Allina Health System Corp.*, 276 F. 3d 1032, 1042 (8th Cir. 2002) ("Certain courts have exploded this limited bar in ways that mock the very purpose and intent of the 1986 Amendments," quoting Congressional correspondence).

A "public disclosure" is defined by the statute in terms of "allegations or transactions, not information." *United States ex rel. Springfield Terminal Ry. v. Quinn*, 14 F. 3d 645, 653 (D.C. Cir. 1994); *Chen-Cheng Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1418 (9th Cir. 1992). Additionally, the statute carefully identifies the limited types of public disclosure that matter. 31 U.S.C. § 3730(e)(4)(A) (essentially describing litigation or administrative hearings, government investigations or reports, and the news media) ("Sec. 3730"). Lacking real public

disclosures, these defendants seek to sell instead what is really a regression to the discarded "government knowledge" standard, arguing that the purported public disclosures on which they rely show that there was available to the United States sufficient "information" about variations in pharmaceutical pricing for various kinds of purchasers that the government could or should have figured out on its own, before Ven-A-Care sued these defendants, that these specific defendants were committing the fraud that Ven-A-Care alleged. In addition to misconstruing the statute, their arguments ignore the vast size of the pharmaceutical industry, the huge number of drugs that hundreds of manufacturers market, and the thicket-like complexities and proprietary confidentialities of the world of pharmaceutical pricing and marketing. Not surprisingly, in their zeal to depose Ven-A-Care from its rightful position atop the caption of these cases, defendants also ignore the indispensable role actually played by Ven-A-Care, an industry insider, in exposing specific defendants and the specific drugs they used to cheat the government programs that reimburse providers for those drugs.

The defendants contend the government already had information about, or should have figured out from disparate sources over time, their own perfidy before Ven-A-Care exposed them in its pleadings by name, by drug and by NDC number. That is not consistent with the law or with the facts in this case. Thus some of the defendants' arguments invoke published information that amounts only to surmise that unspecified manufacturers might, at unspecified times in the future, engage in misconduct similar to that alleged by Ven-A-Care against specific defendants in this case. Under that theory the members of an entire industry could be immunized at any time against current or future False Claims Act liability by even a self-serving suggestion that the industry, or "many" in it, may be or may become corrupt. *United States ex rel. Cooper v. Blue Cross & Blue Shield of Florida, Inc.*, 19 F.3d 562, 566 fn.17 (11th Cir. 1994). Other

arguments advanced are based on information that may have been available to the public, but not through a statutorily-enumerated source or in enumerated disclosures that require inside information of the government to comprehend. Defendants' arguments misconstrue the False Claims Act's public disclosure provisions and undermine the goal of the 1986 amendments to favor under-deterrence rather than over-deterrence of whistleblowers. *Dunleavy*, 123 F.3d at 745-746 ("Concerned about the 'conspiracy of silence' and the prevalence of fraud, Congress sought to reforge the balance between over- and under-deterrence [of whistle-blowers]"). Defendants' motions must be rejected in their entirety.

II. COURTS MUST BE CAUTIOUS OF MISGUIDED WANDERINGS "ON THE TRAIL OF FRAUD"

Defendants contend that the public disclosure bar should knock out Ven-A-Care because the government had enough "information" to be "on the trail" of their fraud before Ven-A-Care filed its actions. Implicit, if not explicit, in these arguments is the idea that these defendants should be immune from any relator's claims because the government could have and should have deduced that some drug manufacturers were cheating Medicare and Medicaid, and could have and should have learned that these defendants, for these drugs, were among the offenders by searching for, collating, comparing and analyzing information that could be in various governmental filing cabinets. This "trail of fraud" rubric has been stated by a number of courts; even this Court has used that phrase occasionally. *See United States ex rel. West v. Ortho–McNeil Pharma, Inc.*, 538 F. Supp. 2d 367, 383 (D. Mass. 2008).

It is critically important, however, that this catchy phrase not be permitted to outgrow the statutory language that it stems from: whether there has been "public disclosure of allegations or transactions" in statutorily enumerated sources. Sec. 3730(e)(4)(A). As noted above, this language was adopted by Congress in 1986 when it expressly repealed the prior "government

knowledge" bar to private qui tam actions. *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 26 (1st Cir. 2009) (1986 amendments "abolish the 'government knowledge' regime entailed by the 1943 jurisdictional bar …. Congress replaced the 'government knowledge' regime with one, as shown by the 'public disclosure' bar, focused on the 'public disclosure of information given to the government.'").

At a minimum, it is clear that the language of "put the government on the trail of fraud" is, at most, shorthand for *public disclosures* of *allegations or transactions*, in *specified sources*, that were sufficient to put the government on the trail of fraud. Indeed, the court in *Springfield Terminal*, the originator of the "trail of fraud" language, expressly discussed this concept in the context of *public* disclosure: "Fraud requires recognition of two elements: a misrepresented state of facts and a true state of facts. The presence of one or the other *in the public domain*, but not both, cannot be expected to set government investigators on the trail of fraud." *Springfield*, 14 F. 3d at 655 (emphasis added).

Non-public information known to the government is not a bar to a whistleblower suit – even if the information provided a trail, gave a loaded hint, pointed an accusing finger, or actually collared the offender. *See, e.g., United States ex rel. Ondis v. City of Woonsocket*, 2009 U.S. App. LEXIS 25298 at *11 (1st Cir. 2009) ("public" means outside the government's bailiwick); *United States ex rel. Feingold v. Adminastar Fed., Inc.*, 324 F.3d 492, 495 (7th Cir. 2003) (in addressing definition of public, "the most germane to [3730(e)(4)] is 'accessible to or shared by all members of the community'"); *United States ex rel. Maxwell v. Kerr-McGee Oil & Gas Corp.*, 540 F.3d 1180, 1185 (10th Cir. 2008) ("we interpret 'public disclosure' to require release of information such that it is generally available and not subject to obligations of confidentiality. Communications made to individuals outside the federal government are not

necessarily public disclosures; rather, there must be further investigation to determine whether the information entered the public domain by such communication"); *United States ex rel. Putnam v. E. Idaho Reg'l Med. Ctr.*, 2009 U.S. Dist. LEXIS 81416 (D. Idaho 2009) (disclosures by government investigators to defendant's employees and independent contractors did not constitute public disclosures).

The government's knowledge or ability to sniff out a trail of fraud is not a disabling factor; only public disclosures are relevant. "Congress thus changed the focus of the jurisdictional bar from evidence of fraud inside the government's overcrowded file cabinets to fraud already exposed in the public domain." *United States ex rel. Findley* v. *FPC-Boron Employees' Club*, 323 U.S. App. D.C. 61, 105 F.3d 675, 684 (D.C. Cir. 1997), quoted in *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720 (1st Cir. 2007); *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1201 (9th Cir. 2009) ("[E]ven when the government has the information, it is not publicly disclosed under the Act until it is actually disclosed to the public"); *Putnam*, 2009 U.S. Dist. LEXIS 81416 at *17 (same); *Maxwell*, 540 F.3d at 1183 (internal information in government's possession was not in public domain, so federal auditor could be relator regarding fraud he uncovered during official investigation); *United States ex rel. Liotine v. CDW Gov't, Inc.*, 2009 U.S. Dist. LEXIS 89719 at *24 (S.D. Ill. 2009) (information disclosed to government not public disclosure unless part of investigation).

Secondly, even as to public disclosures, information in general, or information that generally suggests possible wrongdoing, is not sufficient as a public disclosure of "allegations or transactions." Many courts have noted the different use of language in the public disclosure section ("allegations or transactions") versus the original source section (an original source of "the information on which the allegations are based"). As noted in *Springfield*:

> Courts sometimes speak loosely of barring a qui tam suit because it is based on "publicly disclosed information." But the Act bars suits based on publicly disclosed "allegations or transactions, not information." *Wang v. FMC Corp.*, 975 F.2d 1412, 1418 (9th Cir. 1992) (citations omitted). We too find a distinction between "allegations or transactions" and ordinary "information" as a matter of common usage and sound interpretation of the FCA. The pay vouchers and telephone records disclosed during discovery -- the only public information considered by the district court -- were not in and of themselves sufficient to constitute "allegations or transactions" of fraudulent conduct within the meaning of the FCA jurisdictional bar.

Springfield, 14 F.3d at 653. Again, to constitute a disabling public disclosure under the "trail of fraud" language, there must still have been public disclosure of *allegations or transactions*, in statutorily specified sources. Sec 3730(e)(4)(A). Courts have also been vigilant in respecting the balance that Congress created by only evaluating public disclosures that emanated from specified sources – litigation or administrative hearings, government investigation, audits or reports, and the news media. *See Ondis*, 2009 U.S. App. LEXIS 25298, at *13 ("unless the underlying document itself emanates from a source enumerated in section 3730(e)(4)(A), the second prong of the public disclosure bar is not satisfied"); *Dunleavy*, 123 F.3d at 744 (the list of enumerated sources in § 3730(e)(4)(A) "constitutes an exhaustive rendition of the possible sources" of a public disclosure).

In much the same manner, the now-classic formulation of identifying either the X plus Y (the misrepresented and true facts), on the one hand, or the Z (the fraud), on the other hand, must also be read in context. "In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, *from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.*" *Springfield*, 14 F.3d at 654 (emphasis added); *O'Keeffe*, 131 F. Supp. 2d at 96 (same).

In terms of assessing whether an ostensible public disclosure can ever be sufficient if the

allegations or transactions do not identify the actual wrongdoers, it is critical to remember that any ability to identify the actual wrongdoers from among the more general allegations must turn on whether the information that allegedly pinpoints the wrongdoers was publicly disclosed in a specified source. An analogous situation arose in *Maxwell*, where a prior lawsuit had involved somewhat similar claims of underpayment of royalties on off-shore oil leases. However, in analyzing whether the prior lawsuit constituted a disabling public disclosure, the court drew a distinction between the publicly filed documents in that lawsuit, which made no mention of the particular contracts at issue in the later *qui tam* case, and the settlement document that included some of the contracts at issue in the *qui tam*, but which was not publicly available. *Maxwell*, 540 F.3d at 1186.

The statute must control, and it must be understood in its historical context of an expansion of relator actions and a repeal of the prior government knowledge bar. *Rost*, 446 F. Supp. 2d at 18-19, *aff'd* 507 F.3d 720 (1st Cir. 2007). Since Congress has expressly repealed the ban on *qui tam* suits even where the government had prior *knowledge* of the fraud, it is clear that the courts should not ignore the clear statutory restrictions in the public disclosure provision – public disclosure, in an enumerated source, of allegations or transactions – and ban suits merely because the government was or could have been "on the trail of fraud." This is particularly true where the "trail of fraud" assessment is based on some loose compilation of non-defendant specific information in the public domain, combined with information that may have been available internally to the government. Ultimately, the inquiry is whether the "information put in the public domain … present[ed] so clear or substantial an indication of foul play as to qualify as either an allegation of fraud or a fraudulent transaction upon which a qui tam suit could be based." *Springfield*, 14 F.3d at 656.

As will be discussed in detail in the defendant-specific sections below, there have been no public disclosures of the AWP fraud or allegations or transactions involving these defendants and these drugs so as to deprive this Court of subject matter jurisdiction over Relator's claims. Since Relator does not believe that the cited documents constitute disabling public disclosures of the fraud or of allegations and transactions, it would seem apparent that Relator's defendant- and drug-specific allegations were not "based upon" whatever information was disclosed in the public domain. Since neither the actual market prices nor the NDC-specific reported prices were publicly disclosed in statutorily enumerated sources, Relator's allegations over time of these prices and the spreads between them were not based upon information that had been publicly disclosed as described in the FCA. Should this Court disagree, however, and find that one or several of the documents identified by any particular defendant constituted a public disclosure prior to VAC's filing of its sealed complaint against that defendant, and that VAC's complaint was "based upon" the public disclosure, VAC demonstrates its satisfaction of the "original source" provision of the FCA.

III. VEN-A-CARE HAS SHOWN THAT IT IS AN ORIGINAL SOURCE

The primary arguments regarding VAC's status as an original source made by each defendant are that VAC did not have "direct and independent" knowledge of the information underlying its allegations because, inter alia, VAC received its price information from some third party, *i.e.*, pricing compendia or GPOs; that information was available to many other participants in the pharmaceutical industry; and VAC was not an operating pharmacy at all relevant times or did not actually purchase all of the drugs at issue. *See, e.g.*, Abbott Reply at 10-11 (Master Dkt. #6677), Dey Reply at 11 (Master Dkt. #6681), Roxane Reply at 14 (Master Dkt. #6678). These arguments border on frivolous. First, as discussed in VAC's opposition brief, VAC obtained its

pricing information in exactly the manner intended for a qui tam relator – as a target of the fraudulent scheme alleged. Second, VAC obtained its information precisely how one in its position in the industry ordinarily obtained price information. The bundling or compilation of multiple price lists by the pricing compendia, wholesalers or GPOs did not constitute third party efforts directed at ferreting out this information and analyzing it for fraud.[1] Third, there is no requirement that a relator must have actually participated commercially in the fraudulent acts that he or she observed; that confuses relator jurisdiction with standing. Obviously someone can have information about pricing or other commercial facts without having had a transaction based on that information. Ven-A-Care is, and was at all relevant times, a licensed pharmacy, able to gain access to inside price information that was not available to the general public (or even the government). [Declaration of Susan Schneider Thomas Submitting Exhibits Relied Upon in Ven-A-Care of the Florida Keys, Inc.'s Surreply to Abbott Laboratories Reply in Support of Motion to Dismiss for Lack of Subject Matter Jurisdiction Under the False Claims Act ("Thomas Decl. II") Ex. A, Lockwood Dep. Tr. 4/23/2009, pp. 226; ("Thomas Decl. II") Ex. B, Lockwood Dep. Tr. 7/27/2009, pp. 21:18-22:11]. It is of no moment whether VAC actually purchased any or all of the drugs at issue in the litigation; the only possible "mediation" by another party would have been if VAC had *only* learned of the pricing information through another party's purchases of the drugs. This was not the case. Instead, VAC had full and direct information of the price

[1] In providing prices to its customers, McKesson was simply conducting its regular business – not undertaking an effort to aid VAC in discovering or evaluating whether manufacturers were gaming the system. VAC typically bought inventory from resellers, not from the manufacturers, but it didn't have to buy from a manufacturer to have direct knowledge, independent of any public disclosure, of what it can buy a product for in the marketplace and what the spread is.

information and marketing conduct on which it based its allegations despite not always having consummated transactions based on that price and marketing information.

Finally, despite defendants' unsubstantiated efforts to tarnish VAC's status because VAC's information may have also been received by many others, the FCA "original source" provision does not have any requirement of exclusivity or even narrow availability of information. As various courts have held, the Act refers to "an" original source, not "the" original source, and it is quite possible that multiple sources of the same or somewhat different information concerning fraud might be eligible as relators. *See United States ex rel. Barajas v. Northrop Corp.*, 5 F.3d 407, 410 (9th Cir. 1993); *United States ex rel. Miller v. Bill Harbert Int'l Constr., Inc.*, 519 F. Supp. 2d. 7, 12 (D. D.C. 2007).[2] Indeed, the "first-to-file" bar contemplates exactly that situation. Sec. 3730(b)(5).

The First Circuit just recently rejected a substantially similar "indirect" argument in *Ondis*, reversing the district court and stating:

> The district court found that the relator did not have direct knowledge in part because his employees, rather than he himself, conducted investigatory steps." *United States ex rel. Ondis v. City of Woonsocket*, 582 F. Supp. 2d 212, 220 (D. R.I. 2008). We disagree with this aspect of the district court's reasoning. Merely because a person acts through agents does not necessarily render his knowledge indirect. *See Minn. Ass'n of Nurse Anesthetists*, 276 F.3d at 1049.

United States ex rel. Ondis v. City of Woonsocket, 2009 U.S. App. LEXIS 25298 at *23 (1st Cir.

[2] Presumably hundreds or even thousands of physicians, medical office personnel or company sales and marketing employees had access to substantially the same information about Genotropin as did the relator in *United States ex rel. Rost v. Pfizer, supra*. The courts have recognized that Congress chose not to bring down the public disclosure bar against the lone soldier who stepped forward in those circumstances, though, plainly accepting that the incriminating information may have been out there in other documents that might have been accessible to many industry insiders. Congress' goal was to incentivize at least one such insider to come forward. The government is fully protected against the mixed blessing of too many whistleblowers on the same fraud by the "first-to-file" provision.

2009).

Defendants draw meaningless distinctions between the many cases VAC cited in its Opposition Brief permitting relators to rely on their own investigations and the situation herein. Notably, cases that express concern with relators conducting their own investigations, with or without assistance from others, generally start with a situation in which the relator's investigation was triggered by some public information of the type enumerated by Sec. 3730. *See, e.g., United States ex rel. O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87 (D. Mass. 2001) (relator considered EPA documents and hearings); *United States ex rel. Kreindler & Kreindler v. United Technologies Corp.*, 985 F. 2d 1148 (2d Cir. 1993) (attorneys obtained information from court filing); *United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458 (S.D.N.Y. 2002) (scientific journals likened to news media). That is not the case here where the true pricing data was not accessible to the government and certainly not "to any stranger to the fraud," *Kalmanowitz* at 463. An industry outsider could not obtain these prices (("Thomas Decl. II") Ex. A, Lockwood, John M. 4-23-09, 226:8-227:10).

Defendants' cited cases involve interlopers, not industry insiders. In *O'Keeffe,* 131 F. Supp. 2d at 93, the relator, described by the court as a "gadfly outsider," filed a *qui tam* complaint claiming the defendant engineering companies misrepresented the environmental impact of a commuter rail project. The relator, a co-founder of an environmental rights charitable organization, was not a target or a beneficiary of the misrepresentations that were key to the suit. Similarly, in *Kalmanovitz,* the relator, a foundation that advocated that the defendant alcohol manufacturers caused misrepresentations related to the treatment of alcohol-related diseases also was not a target or beneficiary of the misrepresentations that were key to the suit. The court ruled that Alcohol Foundation's social agenda did not make it a proper relator and

found Congress intended to incentivize "insiders who put their personal employment or other interests at risk in order to vindicate the pecuniary rights of the United States." *Id*. at 465.

The allegations of fraud asserted by Ven-A-Care are that these defendants reported false prices on specified drugs, leading to inflated government reimbursement. Ven-A-Care's claims "did not derive from a third party's research and investigation", rather it "discovered the alleged fraud and Relators conducted the investigation." *Kennard v. Comstock Resources, Inc.*, 363 F.3d 1039, 1046 (10th Cir. 2004). Unlike those cases cited by the Defendants, the information Ven-A-Care received and used as the basis of its qui tam suits was received in the normal course of its business, not from public information or records. Ven-A-Care operated in the market in which the fraud was occurring. The fraud alleged by Ven-A-Care was designed by the Defendants to specifically induce Ven-A-Care and like providers into purchasing their drugs over competitors' drugs. Ven-A-Care was a "close observer" of the fraudulent activity at issue, and therefore is the type of relator Congress intended to incentivize to file a *qui tam* suit. *See*, S. Rep. No. 99-345, 99th Cong., 2d Sess. 4 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5269.

Ven-A-Care discovered this massive fraud on its own, when it observed the ridiculous spreads that were being built into its own reimbursement claims. On its own volition, Ven-A-Care, beginning in the early to mid-'90's, provided pricing data together with an explanation of how specific manufacturers were manipulating their reported prices. That VAC was then asked to also share its information with other persons in the OIG [("Thomas Decl. II") Ex. C, Lockwood 4/24/09 Dep. Tr. pp. 289:5-290:21] does not mean Ven-A-Care's efforts were, as Roxane suggests, at the behest of the government nor diminish Ven-A-Care's status as an original source. Rox. Reply at n. 15 (Master Master Dkt. #6678).

Ven-A-Care has shown it had "first hand knowledge of the alleged fraud" and that it

"obtained this knowledge through [its] own labor unmediated by anything else." *In re Pharmaceutical Average Wholesale Price Litigation*, 538 F. Supp. 2d 367, 384 (D. Mass. 2008), citing *United States ex rel. Aflatooni v.Kitsap Physicians Servs.*, 163 F.3d 516, 525 (9th Cir. 1999). Nothing more is required and Ven-A-Care should be recognized as a laudable and valuable trigger of the AWP price fraud cases currently being litigated by the United States and VAC in this Court.

IV. SPECIFIC ARGUMENTS PERTAINING TO DEY

A. Whether Taken Individually or Collectively, the Disclosures Identified by Dey Did Not Result in a Public Disclosure of Any One or More of Ven-A-Care's Claims

The main argument advanced by Dey in its reply brief concerning the public disclosure bar is as follows: Although any single alleged disclosure, standing alone, may not have revealed all of the essential elements of the misrepresented state of facts and the true state of facts from which an inference of fraud could be drawn, two or more of the disclosures, taken together, comprised a public disclosure of one or more VAC claims. Dey nonetheless fails to piece together, from the numerous putative disclosures it has identified, even one example of an integrated set of disclosures that published the essential elements of any VAC claim in the public domain.[3]

As this Court has previously acknowledged based on the extensive record developed in this MDL over a number of years, different drugs are often marketed, reimbursed, sold and priced in different ways, and for this reason notice of seeming irregularities in one drug's pricing is not necessarily notice of fraud in another drug's pricing. *United States ex rel. Ven-a Care of*

[3] *See De La O v. Housing Auth. of City of El Paso, Tex.*, 417 F.3d 495, 501 (5th Cir. 2005) ("Judges are not like pigs, hunting for truffles buried in briefs.") (quoting *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991)).

the Florida Keys, Inc, et al. v. Abbott Laboratories, Inc., No. 07-11618, 2008 WL 2778808, at *3 (D. Mass. July 15, 2008). The conclusory allegation of one broad scheme is inadequate, and each drug must be analyzed differently. *Id.* Based on the same reasoning, for VAC's claims to have been publicly disclosed, the allegation of fraud or the essential elements of the pricing fraud must have been broadcast with some level of specificity in an enumerated source.

Dey's public disclosure argument is based on the faulty premise that broad, published references to a problem, general reports regarding "'inflated' published prices, 'marketing the spread,' and purported over-reimbursements made by Medicare and Medicaid," Dey Reply at p. 1 (Master Dkt. #6681), and similar information that was not specific to any Defendant and claim or failed to disclose any spread beyond the fairly formulaic spread between WACs and AWPs constitute public disclosures of VAC's claims. However, because this information does not disclose pricing fraud concerning any specific manufacturer or drug, Dey's analysis and conclusion that the essential elements of VAC's claims were exposed to the public at large by these types of disclosures is fundamentally flawed. Such references individually and collectively disclose nothing more than information, not allegations or transactions, and they will not support the finding of a public disclosure under the FCA. *Springfield*, 14 F.3d at 653. An abundance of published information can not elevate its character from information to allegations or transactions, where the collection of enumerated disclosures fails in the end to disclose "so clear or substantial an indication of foul play as to qualify as either an allegation of fraud or fraudulent transaction." *Id.* at 656.

B. Dey's Additional Public Disclosure Arguments Lack Merit

Dey argues that the OIG's June 1996 Pharmacy Report (Dey Ex. No. SJEx48, Master Dkt. #6184), June 1996 Supplier's Report (Dey Ex. No. SJEx49, Master Dkt # 6184) and

November 1998 VA Report (Dey Ex. No. SJEx51, Master Dkt # 6184)[4] contain the essential elements of VAC's albuterol and ipratropium claims against Dey. A summary and analysis of each report is included in the table attached as Ex. B to VAC's response. Dey does not attempt to itemize and connect the information it contends reveals the essential elements of the fraud. Even taken together, the reports do not disclose VAC's claims concerning any drug manufacturer, drug product, actual individual prices, mega-spreads beyond the formulaic spreads expected by the industry and the government, or any fraudulent scheme. The reports thus fail to supply the necessary set of facts from which a reasonable inference of fraud may be drawn, whether or not Dey was identifiable from the reports as one of a narrow set of albuterol manufacturers.

Although all three reports contain information concerning albuterol, even collectively they do not publish the allegation of fraud or the essential elements of fraudulent transactions specific to albuterol products generally, much less to a particular Dey albuterol product. Moreover, the reports concern albuterol in the context of programs, purchasing models, classes of trade, coding systems, and payment methodologies different from those relevant to VAC's claims. The reports contribute nothing to the disclosure of the misrepresented or true set of facts concerning VAC's albuterol claim in the Medicaid and Medicare context against Dey.

Ipratroprium is discussed only in the November 1998 VA Report. The information in the report does not constitute a public disclosure of VAC's ipratropium claims for the same reasons all three reports do not comprise a public disclosure of VAC's albuterol claims.

Together, the July 1987 Lexington Herald (Dey Ex. No. 24, Master Dkt. #6209) and the June 1990 Drug Store News (Dey Ex. No. 26, Master Dkt. #6209) articles referenced by Dey

[4] Erroneously identified in Dey's Reply as an August 1998 VA report.

discuss, in general terms only, that some drug manufacturers' reported inflated prices and marketed the spread; that spreads ranged from 13% to 16% off AWP; that third party reimbursements based on AWPs were not earned discounts; and that manufacturers understood higher AWPs increased sales. The information is unrelated to any manufacturer's specific conduct. The articles do not furnish any information relevant to the misrepresented or true set of facts regarding an actual claim, and add nothing to the previously discussed OIG reports.

Dey asserts that its mega-spreads between WAC and AWP were readily ascertainable from industry pricing compendia, and that those subscription publications qualify as "news media." Dey's contention that industry pricing compendia, sold only by subscription, are "news media" stretches the definition of that term well beyond its ordinary meaning, and Dey does not suggest that Congress used the term differently. *See, e.g., Liotine*, 2009 U.S. Dist. LEXIS 89719 at *20-21 (university's electronic newsletter directed to employees not product of "news media" under Sec. 3730 (e)(4)(A)). But even if an expensive subscription trade service were considered publicly available, in contrast with the definition of "public" that is "most germane" to the public disclosure bar ("accessible to or shared by all members of the community," *Feingold*, 324 F.3d at 495, citing *Hughes Aircraft Co. v. U.S.*, 520 U.S. 939, 952 (1997)),[5] that "does not by any means end the inquiry." *Springfield*, 14 F.3d at 653. The essential question is whether the appearance of Dey's reported prices in such a publication would constitute a public disclosure of "allegations

[5] "As to the second requirement, *i.e.*, the sufficiency of the disclosure as public within the meaning of the Act, we have suggested that Section 3730(e)(4)(A) requires information to be public enough that it 'would have been equally available to strangers to the fraud trasaction had they chosen to look for it as it was to the relator.' *Stinson*, 944 F.2d 1149 at 1155-56. Whether a disclosure is 'public' is a determination influenced significantly by the specific source or context of the disclosure and the particular facts of each case." *United States ex rel. Paranich v. Sorgnard*, 396 F.3d 326, 333 (3d Cir. 2005). There has certainly been no showing that either the pricing compendia or the GPO or wholesaler price lists were publicly disclosed under the FCA.

or transactions" of fraudulent conduct. *Id.* (jurisdictional provision bars only *qui tam* actions that are based on the public disclosure of "allegations or transactions.")

"[I]n common parlance, the term 'allegation' connotes a conclusory statement implying the existence of provable supporting facts." *Id.* at 653-654, citing *Webster's Third New International Dictionary* 55 (1976). "The term 'transaction' suggests an exchange between two parties or things that reciprocally affect or influence one another." *Springfield*, 14 F.3d at 654. In *Springfield* the court found that "both plain meaning and a consideration of the aims of the statute" directed the conclusion that the pay vouchers and telephone records produced in discovery were "public information" but were not sufficient to constitute "'allegations or transactions' of fraudulent conduct" within the meaning of the statute. *Id.* at 653. At most, the court declared, the records provided a vehicle by which the "already suspicious" relator could pursue its investigation. *Id.* at 656. The court recognized that "the task of determining whether 'allegations or transactions' have been 'publicly disclosed' will never be cut-and-dried," but was satisfied that:

> [I]n this case the information put in the public domain did not present so clear or substantial an indication of foul play as to qualify as either an allegation of fraud or a fraudulent transaction upon which a *qui tam* suit could be based.

Id.

Plainly, the publication of Dey's AWPs, or even both its AWPs and its WACs, would not constitute an "allegation" of anything. Similarly, a publication of its reported prices, in and of itself, would not identify a "transaction," much less a fraudulent one.

In summary, the bulk of Dey's asserted public disclosures provide no specifics regarding the elements of fraud pertinent to any particular VAC claim. To the extent any of Dey's statutorily cognizable disclosures may contain some information concerning one VAC claim or

another, even collectively they fall short of disclosing all of the elements of fraud as to any particular VAC claim.

C. Ven-A-Care Is an Original Source As to Its Allegations Against Dey

Dey argues that "the evidence demonstrates that Ven-A-Care merely collected and summarized second-hand information relating to Dey at the request of the Government in connection with a Government-initiated investigation. This is not sufficient to fit Ven-A-Care within the 'original source' exception." Dey Reply at 2 (Master Dkt # 6681). Dey's argument might be persuasive, if its facts were true, which they are not.

In addition to the common arguments discussed in Section III of this surreply, Dey erroneously argues that Rob Vito's investigation preceded Ven-A-Care's allegations of "fraud" against Dey, and that Ven-A-Care did not give the United States its original source information prior to filing its complaint against Dey. The circumstances surrounding Ven-A-Care's disclosure of Dey's fraud are discussed in detail in Ven-A-Care's Response Brief at pp. 40-43. Ven-A-Care did not learn of Dey's fraud from Rob Vito. Instead, it brought to Rob Vito the "industry insider" prices available to Ven-A-Care in the marketplace and showed Mr. Vito the fraud occurring in the marketplace. *See* Jones Decl, Master Dkt. #6645 ¶¶ 14-17 and ("Thomas Decl. II" Ex. D, T. Mark Jones Tr 12/8/2008, pp 800:20-804:13) . Additionally, Ven-A-Care notified the United States of the fraud occurring in the marketplace, and more specifically of Dey's prices for the relevant drugs before filing its initial complaint against Dey. Jones Decl., Master Dkt. #6645, ¶¶ 16-17. Dey argues that because Ven-A-Care did not provide two direct communications between it and Dey to the Government, it can not use those materials to show it was an original source. Substantive pricing material in Ven-A-Care's direct communications with Dey were provided to the Government via Rob Vito prior to Ven-A-Care filing suit. *See*

and compare, ("Thomas Decl."), at Exs. BB (Dkt # 6652-1) and CC. (Dkt # 6652-2); Jones Decl., Exh 2, Tab 51 and Tab 63 (Master Dkt # 6645- 4). As previously discussed, Ven-A-Care obtained the prices as a "close observer" of the fraud and in the normal course of its business. Therefore, the prices given to the Government show Ven-A-Care had direct and independent knowledge of the fraud.

V. SPECIFIC ARGUMENTS PERTAINING TO ROXANE

A. Roxane's Arguments About Public Disclosures Are Based on a Misstatement of the Fraud Alleged in VAC's Complaint

Roxane continues to argue in its Reply that VAC's initial complaint against Roxane did not allege fraud regarding AWPs. However, this Court has already held that the claims in Ven-A-Care's original complaint and Second Amended Complaint involve "the same alleged pricing scheme for the same drug." *In re Pharmaceutical Industry AWP Litigation*, 2007 WL 7572 at *3 (D. Mass. Dec 6, 2007). Therefore, this Court does not need to consider any public disclosures regarding Roxane's Ipratropium after April 10, 2000, the date of Ven-A-Care's original complaint.

The claim of fraud stated in VAC's 2000 complaint is that Roxane's "false and misleading representation of wholesale prices" caused excessive reimbursement by the government for Roxane drugs, including Ipratropium. Indeed, the complaint is replete with references to "wholesale prices." (*see e.g.*, ("Thomas Decl."), Ex. "MM", Docket #6639-40 ¶¶ 56, 59, 60, 68, 86) Contrary to defendant's suggestion otherwise, these "wholesale prices" included AWP, the acronym for "average wholesale price", the price generally and currently paid by providers. Conceptually, "prices to the pharmacies" can only refer to average wholesale prices (AWPs, or prices charged by wholesalers to their customers) because pharmacies do not purchase at wholesaler acquisition cost (WACs). Moreover, not only is AWP is referenced

throughout the original complaint (*id.* ¶¶ 27, 28, 33, 50), but, as this Court has recognized, AWP is a function of WAC. *See In re Average Wholesale Price Litigation*, 491 F. Supp. 2d 20, 26 at fn. 13 (D. Mass. 2007) (AWP is a formulaic counterpart of WAC). Simply put, Ven-A-Care's complaint stated a claim that Roxane reported two different false but mathematically related prices for its drugs with the same result – excessive reimbursement by government programs.

The instant case is not an example of "claim smuggling" of a totally distinct claim, as the Court has jurisdiction over the claims in both the original and the Second Amended Complaint, the opposite of what the Supreme Court concluded in *Rockwell Int'l Corp. v. United States*, 549 U.S. 457 (2007). In *Rockwell*, *id.* at 476, the relator's assertion of a spray-irrigation claim about which he had knowledge and that occurred while he was employed by Rockwell did not provide jurisdiction for his claim of pondcrete insolidity that occurred after the time of his employment. Here, there was no public disclosure of Roxane's AWP pricing fraud either before Ven-A-Care filed its complaint or the amended complaint that further developed that claim.

B. There Were No Public Disclosures of Allegations or Transactions of Pricing Fraud as to Roxane and Ipratropium

The sound bites contained in Roxane's Reply do not demonstrate the "Z", the fraud by Roxane. Sweeping generalities over a twelve year period that AWP is "a joke" or "often picked out of thin air" constitute no more public disclosure of fraud than statements that defense contractors have or might in the future inflate invoices. *See Cooper*, 19 F.3d at 566, fn. 7 ("suppose it was widely believed that there is bid-rigging in the defense industry. Under BCBSF's approach, any disclosure – in a suit against a contractor or a media account of "industry-wide" corruption for instance – could bar a suit by a *qui tam* plaintiff against *any* member of the defense industry. This result is at odds with the purpose of the 1986 amendments.").

The weakness of Roxane's position is best demonstrated by its heavy reliance on a general statement about different drugs made by Congressman Stark in February, 1996, that predates the manufacture and sale of the generic Ipratropium at issue in this case. Roxane Reply Memorandum (Master Dkt #6678) , pp. 8-9. Roxane began selling generic Ipratropium four months later, in June, 1996. *See* Corrected Roxane Local Rule 56.1 Statement of Undisputed Material Facts in Support of Motion for Summary Judgment ("Corr RSJ") (Master Dkt # 6207) ¶ 135. Obviously, there cannot be a public disclosure of a fraud that has not yet occurred. Roxane's argument to the contrary would presuppose prescience, in addition to omniscience, on the part of the government.

In arguing that the "Y", the mega-spread on Roxane ipratropium, was publicly disclosed, defendant points to a February 1996 OIG report involving another drug, again published before Roxane began selling its generic ipratropium. Not surprisingly, Roxane does not cite any cases suggesting that the government is expected to know or assume that a manufacturer will create mega spreads for a new drug. References to pharmacists using AWP in product selection or predictions of what use unnamed manufacturers might make of that information do not disclose the existence of a fraudulent scheme, much less how it worked. Indeed, the May, 1998 OIG report cited by Roxane at pp. 9-10 of its reply only states at p. 6 that "there is the *potential* for manufacturers to manipulate the system." (emphasis added).

Roxane cites no admissible evidence that Congressman Stark's 1999 press release about Medicare reimbursement was a periodic report or available on his website in 1999. It is unlikely that when Congress amended the FCA in 1986, it considered the internet to be "news media", *see Perrin v. United States*, 444 U.S. 37, 42 (1979) ("unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning" at the time Congress

enacted the statute.) Even if it did, however, not "any posting on the internet" constitutes a public disclosure, *see United States ex rel. Liotine v. CDW Government, Inc.,* 2009 WL 3156704 at *7 (S.D. Ill. Sept. 29, 2009). More importantly, Congressman Stark's statement, which he reiterated in 2000, does not mention fraud, Roxane, nor any of the manufacturers of ipratropium. It was a statement about shortcomings of the Medicare program and that Medicare was paying too much in general for the drug. His 2001 statement is subsequent to the Complaint and repeats the discussion of the earlier press releases as examples of an "AWP payment loophole." Similarly, the 2001 GAO report does not mention fraud, nor Roxane, and was published after the 2000 Complaint which includes claims of false price reporting of AWP.

The documents cited at page 4 of Ven-A-Care of the Florida Keys, Inc.'s Combined Opposition to Motions to Dismiss, (Master Dkt. #6638), were referenced not as information on which Ven-A-Care's claims were based, but as examples of Roxane's continuing fraudulent pricing conduct. Roxane's argument that Ven-A-Care's marketing the spread allegations were based on materials obtained in litigation (Roxane Reply Mem. at pp. 15-16 (Master Dkt # 6678)) is simply misleading. In Roxane's attempt to lead this Court down the "trail of fraud," it suggests that the government could or did look at AMPs to identify manufacturers of ipratropium. However, David Tawes did not look at AMPs until 2000, years after VAC brought Roxane's fraud to the attention of the government. Further, AMPs are not publicly published and are irrelevant to an analysis of public disclosure.

C. Ven-A-Care Is an Original Source of the Information Contained in Its 2000 and 2002 Complaints Against Roxane

Ven-A-Care began analyzing confidential price information for Roxane Ipratropium in 1996 and thereafter on a continuing basis as prices came down and utilization increased. [Lockwood Dep. 7/23/08 1076-1077, ("Thomas Decl."), Exh. LL, Master Dkt. #6639-39].

Roxane does not dispute that Ven-A-Care provided DOJ with Medicare AWP spread information on Ipratropium beginning in 1996 and on numerous occasions thereafter. (Tawes 12/13/07 696; 697:5-10, 698:1-15, Master Dkt. #6202-52; Rox Corrected SOF, Master Dkt. #6207, at ¶ 81, Declaration of Mark Jones, ("Jones Decl."), Exh. 2, Tab 75, Master Dkt. #6645-3, ("Thomas Decl. II" Ex. E, VAC-MDL 43246, ("Thomas Decl. II") Ex. F, VAC-MDL 85323-85341 at 85334. Ven-A-Care had this information well before any of the supposed public disclosures alleged by Roxane.

The invoices for Ven-A-Care's purchases of Roxane Ipratropium made before filing its first complaint list AWP as well as the actual prices. (("Thomas Decl. II") Ex. G Lockwood, 7/23/2008, 1138:20-1140:22; ("Thomas Decl. II") Ex. E, VAC-MDL 43246). These invoices are further examples of Ven-A-Care's direct observation of the fraud, *see Chen-Cheng Wang ex. rel. United States v. FMC Corp.*, 975 F.2d 1412, 1417 (9th Cir. 1992).

Additionally, Roxane can not dispute that before the 2000 Complaint, Ven-A-Care provided Congressman Stark with the price and spread data contained in his press release dated September 1, 1999, that was reiterated in 2000 and 2001. Obviously, if Ven-A-Care had this information in its possession before the Congressman's statement, its knowledge was direct and independent, *see Cooper*, 19 F.3d at 568 (relator who provided information acquired from three years of his own research to HCFA about BCBSF's wrongdoing before hearing announcing investigation into BCBSF was an original source).[6]

Ven-A-Care also discussed its claims with the DOJ in early 2000 [Lockwood Dep. 3/17/2008, 590:1-16, ("Thomas Decl."), Exh. S, Master Dkt. #6639-20]. Ven-A-Care continued

[6] Roxane acknowledges that provision of this information to Congressman Stark by Ven-A-Care demonstrates Ven-A-Care's independent knowledge of the Ipratropium AWP fraud, Roxane Response at fn 7.

to provide the government with information about Roxane's AWP fraud including in a presentation to the United States Attorney in Boston in January, 2001. ("Jones Decl.") Tab 119, Master Dkt. #6645-3). Roxane admits that "[t]he OIG obtained pricing information related to ipratropium bromide from VAC by early 2001" (Rox Corrected SOF ¶ 86). In addition, Ven-A-Care provided its analysis and pricing information to the GAO for its 2001 report ("Thomas Decl.", Exh. S, Master Dkt. #6639-20). This evidence demonstrates that Ven-A-Care had direct and independent knowledge of the expanded information about Roxane's false reporting of AWPs stated in the Second Amended Complaint even if there existed a public disclosure of allegations and transactions of fraud regarding Roxane's Ipratropium prior to that Complaint.

Further, Roxane has admitted that Ven-A-Care is also an original source for the allegations about the drugs added in its 2005 Third Amended Complaint, having possession of and providing pricing and spread information on the Additional Drugs on eleven occasions between 2000 and 2002. Rox. Corrected SOF ¶¶ 91, 93-95; *see also* Lockwood 2003 analysis of prices of Additional Drugs ("Thomas Decl. II" Ex. H, VAC-MDL 095517 and "Thomas Decl. II" Ex. I, Lockwood Dep. Tr. 6/19/09 115, 116:1-9).

Simply stated, there is voluminous evidence that Ven-A-Care qualifies as an original source for each allegation and transaction contained in its complaints against Roxane.

VI. SPECIFIC ARGUMENTS PERTAINING TO ABBOTT

A. There Were No Disabling Public Disclosures As to Abbott

In its reply brief, Abbott makes essentially the some arguments it made in its opening brief; indeed, the very documents that it cites are generally the same ones, for the same propositions: e.g., reference to "the head of CMS" having learned that there could be enormous spreads on solutions (Abbott Reply, p. 1 (Master Dkt. #6677)) – same reference as Bruce

Vladeck testimony discussed in opening brief and explained in VAC's Opposition brief as not being relevant because pertaining to different, hospital class of trade (Opp. Mem. at 18 (Master Dkt. #6638)); reference to Barron's article of 1996 (Abbott Reply, p. 1 (Master Dkt. #6677)), already discussed at length in opening brief and explained in VAC's Opposition brief as post-dating VAC's allegations of marketing the spread (Opp. Mem. at 22 (Master Dkt. #6638)); and the Lexington Herald article, which VAC already explained did not name Abbott or allege fraud. (Opp. Mem. at 20-22 (Master Dkt. #6638)). Ven-A-Care has thoroughly discussed the "trail of fraud" language that Abbott erroneously relies upon to fill in the gaps on every one of its purported "public disclosures." Basically, the "trail of fraud" cannot supplant the three statutory elements of public disclosure – public disclosure, through enumerated sources, of allegations or transactions essentially similar to the relator's. *See* pages 30-31, above.

This section, therefore, will address only the one new argument that Abbott advanced regarding a prior public document – a 1992 OIG report concerning dialysis drugs in the End-Stage Renal Disease (ESRD) program under Medicare. (Abbott Exh. L (Master Dkt. #6183-13)). Initially, the only drug at issue in this litigation that was discussed in that report was vancomycin. Obviously, therefore, no argument arises that this was a public disclosure regarding the other three drugs at issue. More fundamentally, however, Abbott's description of this report is exaggerated and misleading in several ways. First, the report does not name Abbott, nor does it publish Abbott's reported or actual vancomycin prices. Second, the report only makes two statements about the prices for unspecified vanco products on an overall basis and it also contains information suggesting that the median price is not particularly informative as to any particular manufacturer's products. Third, the report is focused on invoice prices to End-Stage Renal Disease providers, specifically dialysis centers. Overall, while Abbott's

description would have the reader believe that this report was "all about vanco," and AWP fraud in the Medicaid and Medicare Part B programs, in fact the focus was on changing the reimbursement mechanism for the specific ESRD program under Medicare Part A, where the separately billable drugs were but a small percentage of overall costs. Exh. L, p 4 (Master Dkt. #6183-13).

Obviously, the parties disagree about the significance of a supposed public disclosure not even naming the particular defendant, with this Court having previously recognized the significance of this missing information. *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Actavis*, 2009 U.S. Dist. LEXIS 92945 at *10 (D. Mass. 2009). But this 1992 OIG report is missing more than just any mention of Abbott. Instead, the report only provides information on some unidentified median AWP for a vanco drug, which it then compared to an average acquisition cost. *See* Exh. L, (Master Dkt. #6183-13).

There is no basis on which to conclude that the selected median AWP was an Abbott-reported price. Indeed, Abbott's Statement of Undisputed Additional Facts in the summary judgment context suggests that Abbott has already determined that Abbott's AWP for vancomycin was different.[7] FDB's Red Book itself is not a statutorily enumerated source, so even if one could seek to match OIG's selected median generic AWP and check it against all matching NDCs in Red Book, that would not be a public disclosure. *See* Sec 3730(e)(4)(A).

[7] "OIG documents from a 1991 invoice study showed that dialysis clinics were purchasing Vancomycin at discounts of about 80% off of AWP. For example, OIG notes reflect that in 1991, Abbott's AWP for Vancomycin was $24.88. (Ex. 98 (HHD200-0016)). (Master Dkt. #6465-1) One of the collected invoices from the same year reflects sales of Vancomycin at $4.59 – a discount of nearly 82%." ((Ex. 99 (HHD200-1431) (Master Dkt. #6465-1) Abbott Laboratories Inc.'s Rule 56.1 Statement Of Additional Facts That Preclude Summary Judgment In Favor Of The Government, ¶ 83. (Master Dkt. #6448) The OIG internal documents, of course, are not public disclosures. Moreover, the one lone invoice that was referenced hardly demonstrates an "invoice study" or gives significant information about prices across the board.

While it may be that OIG knew whose price it was, that fact was not publicly disclosed and is thus not cognizable under a public disclosure analysis. Again, as discussed above, it is not the government's information that is relevant; only publicly disclosed allegations or transactions matter. *E.g.*, *Meyer*, 565 F.3d at 1201 ("[E]ven when the government has the information, it is not publicly disclosed under the Act until it is actually disclosed to the public"); *Rost*, 507 F.3d at 728 ("In our view, a 'public disclosure' requires that there be some act of disclosure to the public outside of the government.")

Secondly, the actual statement about vancomycin prices itself fails as a disclosure of allegations or transactions. There is merely a reference to some median generic AWP, and a median acquisition cost, without a clear connection between the two; no NDCs are identified. Further, the report notes that one of the surveyed ESRD facilities paid $41.18 for 1 g vancomycin with an AWP of $31.14, p XX, and that 12 of the surveyed facilities paid at or below the median generic AWP of $19.17 for Vancocin/vancomycin, 500 mL (in unspecified dosage size) while 9 paid above. *Id*. at 6. The OIG report does nothing to carefully report actual prices charged by wholesalers for Abbott's vanco, which at the time was relatively new to the market.

Finally, the 1992 OIG report only surveyed dialysis clinics providing ESRD treatment under Medicare Part A for renal patients. Abbott has made no showing that this limited group represented a fair sample of the types of retail providers that participate in Medicaid and Medicare Part B.

Accordingly, even Abbott's "new" public disclosure does not rise to statutory significance, either alone or with the prior discredited documents.

B. Ven-A-Care Was an Original Source of Information As to Abbott's Fraud

Abbott is simply wrong that Ven-A-Care is not an original source of the allegations in its complaints concerning Abbott. Ven-A-Care does have direct and independent knowledge of Abbott "marketing the spread." Abbott argues that Ven-A-Care fails to be an original source of "marketing the spread" information because it didn't have what it claims to be "direct marketing" from Abbott. Abbott used resources such as GPOs and wholesalers to market its false inflated spreads to industry insiders such as Ven-A-Care. The fact that the spreads were marketed through GPOs and wholesalers does not make Ven-A-Care's information less direct or independent. In fact, Ven-A-Care has testified that the spreads created by Abbott were obvious to customers, such as Ven-A-Care, and that Abbott marketed the spread to its customers by sending the contracts and price lists to its customers, such as Ven-A-Care. ["Thomas Decl. II" Ex. J, T. Mark Jones Dep. Tr., 3/19/2008, 401:4-18 and 406:4-407:1]. Since Ven-A-Care received price lists and catalogues containing the prices of the Abbott's drugs at issue revealing the false, inflated spreads at issue, Ven-A-Care has direct and independent knowledge of the information upon which its allegations are based.

VII. A CORPORATION MAY BE A RELATOR AND AN ORIGINAL SOURCE

Notwithstanding Abbott's suggestion to the contrary, the court in *Minn. Ass'n of Nurse Anesthetists,* 276 F.3d at 1048, fn. 12, citing the background and legislative history of the 1986 amendments to the FCA, specifically rejected the argument that a corporation could not be a relator; *see, United States ex rel. Branch L.L.C. v. Allstate Ins. Co.*, 2009 WL 3353314 at *17 (E.D. La. Oct. 19, 2009) (citing *Allina* with approval and considering statutory language by implication in holding that a corporation could have direct knowledge). To hold otherwise would obviate the long line of cases permitting corporations, authorities, states and other entities

to act as relators, as well as the fact that Congress itself referred to persons as original sources. *See* Section 3730(e)(4)(A) (exception to public disclosure bar if "person bringing the action is an original source").

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Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that on December 18, 2009, I caused a true and correct copy of the foregoing Surreply to Reply Briefs of Abbott, Dey, and Roxane in Support of Motions to Dismiss for Lack of Subject Matter Jurisdiction to be served via LEXIS File & Serve electronic filing service pursuant to CMO #2 in this case.

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